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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,684	01/10/2002	Eric M. Nelson	P-LX 4948	2349
23601	7590	02/23/2005	EXAMINER	
CAMPBELL & FLORES LLP 4370 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122			DAVIS, DEBORAH A	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/914,684	<b>Applicant(s)</b> NELSON ET AL.	
	<b>Examiner</b> Deborah A Davis	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10-5-04.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### DETAILED ACTION

1. Applicants' response to the Office Action mailed on May 17, 2004 has been acknowledged. Currently, claims 1-7 are pending and under consideration. Currently claims 1, 4, and 5 has been amended.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al (USP#6,024,919) in view of David R. Moorman (USP#5,820,826).

Nelson et al teaches a method and apparatus for controlling the absorption of a liquid sample. Nelson et al provides a method and apparatus of manufacture for receiving a liquid sample, such as blood and other body fluids (column 2, lines 47-50) where a first portion of the polymer layer overlies a solid surface and a second portion of the polymer layer overlies a window (see abstract). Sonic treatment of the polymer layer will selectively reduce the void volume of a sintered polymer layer such as a porous high-density polyethylene (see abstract). The apparatus contains a reaction layer comprising reagents that can react with specific analytes in a liquid sample (column 2, lines 61-62). The apparatus has an air gap (column 6, lines 45-49) comprising a space or hole between two separate solids (see Figure 2, 4b) and a

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reflectance monitor (translucent window) for view color reactions and changes in the reaction layer (column 9, lines 58-65). The apparatus also comprise of at least one sidewall and wherein the layers, walls and window define an air gap (see abstract and Figure 2). Nelson et al teaches an absorbent polymer of BIODYNE A 0.65  $\mu\text{m}$  (col. 12, lines 12-13) that is permeable to gases and liquid (col. 3, lines 36-40). With respect to the limitation "such that the air pressure of the air gap is increased, thereby controlling liquid sample absorption by the absorbent layer" it is the Examiner's position that since the Nelson et al reference teaches the same type of absorbent layers taught in applicant's specification (BIODYNE), it is inherent that the air gap will increase when liquid is applied.

Although the reference of Nelson et al teaches a translucent window layer which is defined by the examiner as being the reflectance monitor, the reference is silent with respect to the monitor being attached to the handle of the apparatus. However, the reference of Moorman teaches a test strip apparatus that includes a casing to house the strips. The entire apparatus is placed on an inert support which serves to give added strength to the apparatus and may be transparent if reading from the bottom of the strip element is desired, the attachment may be by double stick tape, hardened hot melt adhesives or a combination of the two (column 11, lines 39-47).

I would have been obvious to one of ordinary skill in the art to modify the reference of Nelson et al to include attaching the reflectance monitor at the bottom of the apparatus as taught by Moorman because this serves to strengthen the apparatus.

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One of ordinary skill in the art would be motivated because appropriate placement of a viewing window on the apparatus can facilitate the analysis of a test fluid.

### ***Response to Arguments***

4. Applicant argue that the reference of Nelson does not teach that the absorbent layer with the viewing surface has a handle with a hole therethrough, the hole defining at least one sidewall of the handle; and a translucent window layer attached to the handle. This argument is noted but not found to be persuasive.

In response, the reference of Nelson teaches a handle (figure 4) with a hole therethrough wherein the hole defines at least one sidewall of the handle and a translucent window layer (figure 5). However, Nelson et al does not provide a teaching of the translucent window layer being attached to the apparatus. Therefore, Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection above.

### ***Conclusion***

5. No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

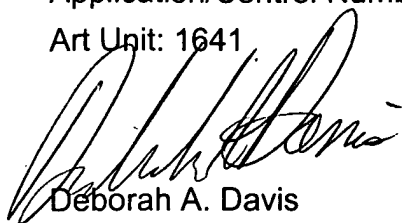
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 17, 2005



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02/18/05